

REMARKS

Amendments to the Claims

Claims 1, 25, 42 and 57 have been amended. Claims 17, 32, 37 and 53 have been cancelled. New claims 67-70 have been added. Support for the amendments to the claims is found in the specification at paragraph 20 and the claims as originally filed. Support for new claims 67-70 is found in the specification at paragraphs 16 and 17.

Rejection of the Claims

In the Official Action dated January 12, 2006, the Examiner rejected claims 1, 3-4, 9-12, 18 and 20-22 under 35 U.S.C. §102(b), as being anticipated by Slovak (U.S. 5,058,605).

Claims 2, 5-8, 19, 23-27, 33-41, 43-44, 49-53, 55, 57-59 and 64-66 were rejected under 35 U.S.C. §103(a) as being unpatentable over Slovak (U.S. 5,058,605).

Claims 13-16, 28-31, 45-58 and 60-63 were rejected under 35 U.S.C. §103(a) as being unpatentable over Slovak (U.S. 5,058,605) in view of Jarding et al. (U.S. 6,035,236).

Additionally, claims 17, 32, 42, 54 and 56 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Slovak (U.S. 5,058,605) in view of Fabian et al. (U.S. 5,431,625).

The Applicant respectfully traverses these rejections and in view of the following arguments and amendments requests reconsideration and withdrawal thereof.

§102(b) Rejection of Claims 1, 3-4, 9-12, 18 and 20-22 over Slovak (U.S. 5,058,605)

The Applicants respectfully disagree with the Examiner's interpretation of the Slovak disclosure and application thereof to the pending claims. As taught at col. 2, lines 20-25 and col. 5, lines 48-51, Slovak is clearly directed to a non-invasive application of DC current. In contrast, the invention described by pending claim 1 clearly requires penetration of the skin and muscle by the needles to a depth sufficient to extend into the area of the proximal and distal motor points of the muscle. One skilled in the art will recognize that the indicated motor points are not in the area of the muscle adjacent to the skin. Support for the amendment to claim 1 setting forth the depth of needle insertion is found in the specification at paragraph 20.

To further clarify the inventive method, claim 1 has been amended by incorporation of the subject matter of claim 17. Thus, the method described by pending claim 1 requires a two second ramp up and a two second ramp down when applying the electric current to the muscle.

The Applicants respectfully submit that Slovak et al. neither teaches nor suggests a method wherein needles are inserted into the muscle a depth sufficient to reach the area of the proximal and distal motor points. Further, Slovak et al. does not teach or suggest the use of a two second ramp up and ramp down for application of the electric current. Therefore, in view of the foregoing differences between the cited art and the pending claims, the Applicants respectfully submit that claims 1, 3-4, 9-12, 18 and 20-22 are not anticipated by Slovak. Accordingly, reconsideration and withdrawal of the §102 rejection is requested.

§ 103(a) Rejection of Claims 2, 5-8, 19, 23-27, 33-41, 43-44, 49-53, 55, 57-59 and 64-66 over Slovak. (U.S. 5,058,605)

Dependent claims 2, 5-8, 19 and 23-24 depend from claim 1 which is believed to be in allowable condition. Therefore, the Applicants submit that these claims are also in allowable condition.

Further, the Applicants traverse the rejection of the pending claims as being obvious over Slovak. In the rejection of the dependent claims for obviousness, the Examiner stated that “one of ordinary skill in the art, furthermore, would have expected the Applicant’s invention to perform equally well with the therapeutic pulses as taught by Slovak,” However, the Examiner has not any facts to support of this conclusory statement. The Applicant respectfully submits that the Examiner’s assumptions must be supported by clearly identified facts in the prior art. See, Ex Parte Stern, 1379, 1381 (B.P.A.I 1989) (“deeming” a result is insufficient to support a § 103 rejection). Therefore, in this instance, the Examiner has failed to establish a prima facie basis for rejecting the pending claims over Slovak.

Further, the Applicants respectfully submit that the passage of time since the Slovak disclosure demonstrates the non-obviousness of the current invention. Secondary considerations, such as long felt need, are essential components of the obviousness determination. In re Rouffet, 47 U.S.P.Q.2d 1453, 1456 (Fed. Cir. 1998). Clearly, the treatment of stroke victims constitutes a long felt need in the medical field. Although significant efforts have been made to provide treatments suitable for overcoming the detrimental impact of stroke, the cited art does not teach or suggest a method which yields the results demonstrated by the current invention. Further, while the Slovak disclosure was available to the public in 1991, the intervening time period has not produced a treatment which provides the results described by the pending application. Thus, the Applicants

respectfully submit that the current invention clearly provides objective evidence of non-obviousness by satisfying a long felt need in the field of stroke treatment.

With regard to Claim 25 and 57 these claims have been amended to better define the current invention. In particular, amended claims 25 and 57 are directed to a method wherein at least two needles are inserted into the muscle to be treated. One needle is inserted to a depth such that it extends into the area of the distal motor point while the other needle is inserted to a depth suitable to reach the area of the proximal motor point. Thereafter, the needles are connected to a source of electricity suitable for providing a current to the muscle. At the beginning of the electrical stimulation, current is ramped up over a two second period. At the end of the stimulation period, current is ramped down over a two second period. Further, the current is applied as a biphasic waveform at a specified pulse count and pulse width. As set forth in claim 25, the current is cycled between periods of rest and stimulation for set periods of time ranging from about 5 minutes to about 15 minutes with stimulation lasting about 5 to about 50 seconds and rest or muscle relaxation being between about 5 and 50 seconds. In claim 57, the current is cycled for a 15 minute time period with the periods of stimulation and rest being about 10 seconds each.

As noted above, the Slovak disclosure expressly teaches away from invasive treatments such as described by the pending claims. In view of the specific teachings of Slovak concerning the treatment points and the use of a non-invasive procedure, one skilled in the art would not be motivated to modify the methods of Slovak in the manner suggested by the Examiner. Therefore, the Applicants respectfully submit that the Slovak disclosure does not render the pending claims obvious. The Applicants request reconsideration and withdrawal of this rejection over Slovak.

§103(a) Rejection of Claims 13-16, 28-31, 45-48 and 60-63 over Slovak (U.S. 5,058,605) in view of Jarding et al. (U.S. 6,035,236)

In the rejection of the referenced claims as being obvious over the combination of Slovak in view of Jarding et al., the Examiner stated that “Jarding teaches it is known to use conductive gel to administer electrical stimulation as set forth in column 4, lines 41-57, for the purpose of delivering electrical stimulation therapy.” The foregoing arguments over Slovak are equally pertinent to this rejection; however, for the sake of conciseness the arguments will not be repeated. The Applicants respectfully traverse this rejection.

The Applicants submit that the Examiner has fallen prey to the temptation of hindsight reconstruction in the formulation of this rejection of the pending claims. As a result, the Examiner has not fulfilled the obligation of considering the current invention as a whole as required by Ruiz v.

A.B. Chance Co., 69 U.S.P.Q.2d 1686, 1690 (Fed. Cir. 2004). As noted by the Ruiz Court, “the ‘as a whole’ instruction prevents evaluation of the invention part by part. Id. Thus, breaking the current invention into individual components and finding references which appear to equal those components does not support a §103 rejection. Rather, as noted by the Ruiz Court, the proper showing is not the desired result of the invention but a showing that one skilled in the art “confronted by the same problems ... would select the various elements from the prior art and combine them in the claimed manner.” Id. Finally, “obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching suggestion or incentive supporting the combination.” In re Geiger, 2 U.S.P.Q.2d 1276, 1278 (Fed. Cir. 1987).

The Jarding et al. reference, like Slovak, does not teach or suggest the step of locating either the proximal or distal motor points of a muscle by using an electric probe in conjunction with conductive gel. Further, Jarding et al. does not teach or suggest the use of a needle penetrating a muscle. Rather, Jarding et al. at col. 4, lines 41-57 merely describe the use of electro-conductive gel during the administration of a micro-current. Further, neither Jarding et al. nor Slovak teach or suggest the step of locating the distal and proximal motor points as described by the pending claims. Thus, the Examiner’s conclusory statement that “it would have been obvious ... to have modified the delivery of electrical stimulation as taught by Slovak with the electro-conductive gel as taught by Jarding et al., in order to test and determine the proper position of the conductive need before insertion” clearly demonstrates an attempt to use hindsight reconstruction to yield the current invention. However, in this instance neither of the cited references support the conclusion reached by the Examiner, as neither reference teaches or suggests the steps of finding the proximal or distal motor points of the muscle and treating the muscle by an electric current transmitted through needles penetrating the muscle.

In view of the improper combination of the cited art and the failing of the art to teach or suggest the process set forth in pending claims 13-16, 28-31, 45-48 and 60-63, the Applicants respectfully submit that the pending claims are not obvious in view of the cited art. The Applicants respectfully request reconsideration and withdrawal of the rejection of pending claims 13-16, 28-31, 45-48 and 60-63 over Slovak in view of Jarding et al.

§ 103(a) Rejection of Claims 17, 32, 42, 54 and 56 over Slovak (U.S. 5,058,605) in view of Fabian et al. (U.S. 5,431,625)

The Applicants respectfully traverse the rejection of claims 17, 32, 42, 54 and 56 over Slovak in view of Fabian et al. The foregoing arguments concerning Slovak and hindsight reconstruction are equally applicable to this obviousness rejection and will not be repeated for the sake of conciseness.

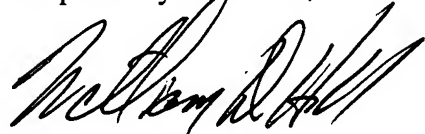
Specifically as to the Fabian et al. reference, the Applicants note that Fabian et al. describe a non-invasive treatment method. Specifically, at col. 1, lines 18-22, Fabian et al. state, “Iontophoresis medication delivery systems transfer ionized molecules of a drug solution through a patient's skin. Drug migration is achieved by placing two electrodes on the patient's skin which are connected to an electric direct-current (DC) power supply.” (emphasis added) Clearly, Fabian et al. does not teach or suggest a method for treating muscles weakened by cerebrovascular disease. Further, Fabian et al. do not teach or suggest the ramping up and ramping down of electric current provided to the muscle via needles penetrating into the areas of the proximal and distal motor points. Therefore, the Applicants respectfully submit that the pending claims are not obvious in view of the combination of Slovak with Fabian et al. Accordingly, the Examiner is requested to reconsider and withdraw the rejection of the pending claims over the combination of Slovak in view of Fabian et al.

Conclusion

In view of the foregoing amendments to the claims and arguments over the cited art and rejections of the claims, the Applicants respectfully request reconsideration and withdrawal of the indicated rejections. A formal Notice of Allowance of Pending Claims 1-16, 18-31, 33-36, 38-52, and 54-70 is requested.

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Respectfully submitted,



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